IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS
STATE OF MISSOURI

STATE OF MISSOURI, ex rel.	)	
JEREMIAH W. (JAY) NIXON,	)	
Attorney General,	)	
	)	
AND	)	
	)	
MISSOURI DEPARTMENT OF	)	
SOCIAL SERVICES, DIVISION OF	)	
MEDICAL SERVICES,	)	
Plaintiffs,	)	
vs.	)	Case No:
	)	
DEY, INC., a Delaware corporation	)	Division:
Serve: The Corporation Trust Company	)	
Corporation Trust Center	)	
1209 Orange Street	)	
Wilmington, DE 19801	)	
	)	
DEY, L.P., a Delaware limited partnership	)	
Serve: The Corporation Trust Company	)	
Corporation Trust Center	)	
1209 Orange Street	)	
Wilmington, DE 19801	)	
	)	
MERCK KGaA, a foreign corporation	)	
Serve: Merck KGaA	)	
Frankfurter Str. 250	)	
64293 Darmstadt	)	
Germany	)	
	)	
EMD PHARMACEUTICALS, INC.,	)	
a North Carolina corporation,	)	
Serve: CT Corporation System	)	
225 Hillsborough Street	)	
Raleigh, NC 27603	)	
	)	
WARRICK PHARMACEUTICALS	)	
CORPORATION, a Delaware corporation	)	
Serve: The Corporation Trust Company	)	
Corporation Trust Center	)	
1209 Orange Street	)	
Wilmington, DE 19801	)	

SCHERING-PLOUGH CORPORATION,	)
a Delaware corporation	)
Serve: The Corporation Trust Company	)
Corporation Trust Center	)
1209 Orange Street	)
Wilmington, DE 19801	)
	)
SCHERING CORPORATION,	)
a New Jersey corporation,	)
Serve: Joseph J. Larosa	)
2000 Galloping Hill Rd.	)
Kenilworth, NJ 07033	)
	)
Defendants.	)

FIRST AMENDED PETITION FOR FALSE CLAIMS, FRAUDULENT MISREPRESENTATIONS AND UNLAWFUL TRADE PRACTICES

Plaintiffs, State of Missouri and Missouri Department of Social Services, Division of Medical Services, at the relation of the Attorney General of the State of Missouri, Jeremiah W. (Jay) Nixon, in his official capacity, by the undersigned Assistant Attorneys General, state the following:

I. PRELIMINARY STATEMENT AND NATURE OF THE ACTION

1. This action is brought for and on behalf of the Plaintiffs under the common law, the Missouri Health Care Payment Fraud and Abuse Act (hereinafter sometimes referred to as "MHCPFAA")[1], Section 191.900 *et seq.,*[2] and the Missouri Merchandising Practices Act ("MMPA"), Section 407.010 *et seq*. The Plaintiffs (hereinafter sometimes referred to as the

[1]For the convenience of the court, Plaintiffs attach a list of all acronyms used herein as Exhibit B.

[2]All statutory references are to Mo. Rev. Stat. (2000), as presently amended, unless otherwise indicated.

"Attorney General") seek restitution, monetary damages, pre-judgment interest, civil penalties for each unlawful act, three (3) times the amount of damages which the State and Federal Government sustained, declaratory and injunctive relief, disgorgement of unlawful gains, recovery of costs, attorneys' fees, expenses and punitive damages.

2. Each of the Defendants is or has been engaged in the business of manufacturing, marketing and selling prescription drugs throughout the United States. The principal payors for such prescription drugs are federal and/or state governments (under, respectively, the Medicare and Medicaid Programs), private insurers and self-insured employers (Third-Party Payors), and private individuals (Patients), including elderly patients who make payments for drugs under the Medicare program.

3. The Defendants knowingly and intentionally made false representations of prices, costs and sales for certain of their inhalation drugs directly or indirectly to the Missouri Medical Assistance Program which is commonly known as the Missouri Medicaid Program (MMP).

4. The Attorney General brings this action to return to the State and its taxpayers the increased payments for prescription drugs disbursed as a result of the Defendants' wrongful conduct and to disgorge from these Defendants the excessive profits they received as a result of the artificially inflated average wholesale price ("AWP") and/or the artificially inflated wholesaler acquisition cost ("WAC") of a prescription drug, which is part of a "marketing the spread" scheme, accomplished by the Defendants through violations of law.

II. PARTIES

5. Plaintiffs are the State of Missouri at the relation of the Attorney General of the State of Missouri pursuant to the authority of Section 27.060, Section 407.020 and Section 191.905 and Missouri Department of Social Services, Division of Medical Services pursuant to

Section 208.201.

6. Jeremiah W. (Jay) Nixon is the duly elected, qualified and acting Attorney General of the State of Missouri.

7. The Missouri Department of Social Services ("DSS") and its Division of Medical Services ("DMS") are agencies of the executive branch of the government of the State of Missouri, as authorized by Article IV, Sections 12 and 37 of the Constitution of Missouri and Section 208.201.

8. Defendant Dey, Inc. f/k/a Dey Laboratories, Inc. ("Dey") is a corporation organized under the laws of Delaware with its principal offices in Napa, California. At all times material to this civil action, Dey has transacted business in the State of Missouri by, including but not limited to, selling and distributing to purchasers in the State of Missouri prescription drug products including Albuterol, Albuterol Sulfate and Ipratropium Bromide. Dey, Inc. is the general partner of Dey, L.P. a limited partnership organized and existing under the laws of the State of Delaware.

9. Defendant Dey, L.P., is a limited partnership organized under the laws of Delaware with its principal offices in Napa, California. Dey, L.P. is joined as a Defendant by serving its general partner, Dey, Inc. At all times material hereto, all acts committed by or on behalf of Dey, Inc. were also committed by or on behalf of Dey, L.P., a limited partnership and Dey, Inc. and Dey, L.P. are referred to herein collectively as Dey. Upon information and belief, Dey, L.P. was formerly known as Dey Laboratories, L. P. and all acts committed by or on behalf of Dey Laboratories, L.P. and Dey, L.P. were performed and committed by and through the general partner, Dey, Inc., formerly known as Dey Laboratories, Inc.

10. Defendant Merck KGaA ("Merck") is a foreign corporation with headquarters in

Darmstadt, Germany. At all times material to this civil action, Merck transacted business in the State of Missouri by, including but not limited to, selling and distributing prescription drug products to providers and purchasers in the State of Missouri. Merck is affiliated with Merck Sante S.A.S., Merck S.A., Merck-Lipha and Lipha.

11. Defendant EMD Pharmaceuticals, Inc., ("EMD") is a corporation organized under the laws of North Carolina with its principal offices in Durham, NC. At all times material to this civil action, EMD transacted business in the State of Missouri by, including but not limited to, selling and distributing prescription drug products to providers and purchasers in the State of Missouri. EMD is a subsidiary of Merck KGaA.

12. Defendant Warrick Pharmaceuticals Corporation ("Warrick") is a corporation organized under the laws of Delaware with its principal offices and operations in the State of New Jersey, sometimes alleged to be in Reno, Nevada. At all times material to this civil action, Warrick has transacted business in the State of Missouri by, including but not limited to, selling and distributing Albuterol and Albuterol Sulfate solution to providers and purchasers in the State of Missouri.

13. Defendant Schering-Plough Corporation ("Schering-Plough") is a corporation organized under the laws of New Jersey with its principal offices in Madison, New Jersey. At all times material to this civil action, Schering-Plough and its subsidiaries have transacted business in the State of Missouri by, including but not limited to, selling and distributing prescription drug products to providers and purchasers in the State of Missouri.[3]

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[3]Schering Laboratories is described as the U.S. pharmaceutical arm of Schering-Plough Corporation, and appears to be the operating unit of Schering-Plough through which Schering-Plough conducts much of its pharmaceutical business. It is unclear at this point whether Schering Laboratories exists as a separate corporate entity. Schering Laboratories is not

14. Defendant Schering Corporation ("Schering") is a corporation organized under the laws of New Jersey with its principal offices located at 1 Giralda Farms, P.O. Box 1000, Madison, New Jersey 07940. Schering also maintains a corporate address at 12125 Moya Blvd., Reno, Nevada, 89506-2600, the same corporate address of Warrick. At all times material to this civil action, Schering has transacted business in the State of Missouri by, including but not limited to, selling and distributing prescription drug products to providers and purchasers in the State of Missouri.

15. Defendant Schering-Plough is a stock holding company and Schering is the direct parent corporation of Warrick. It is unclear at this point which of the multiple subsidiary corporations and businesses associated with Schering and Schering-Plough are the actual manufacturers, marketers, sellers, and/or suppliers of some or all of the products involved in this litigation and which are Warrick's actual parent(s) or shareholder(s). Therefore, the State joins Schering and Schering-Plough ("Schering/Schering-Plough") in this petition.

THE COURT SHOULD DISREGARD THE CORPORATE FICTION FOR WARRICK, SCHERING, AND SCHERING-PLOUGH

16. The corporate fiction may be disregarded when the corporate form has been used as part of a basically unfair device to achieve an inequitable result, specifically when the corporate fiction is used to perpetrate a fraud, as a mere tool or business conduit of another corporation, as a means of evading existing legal obligations, to achieve or perpetrate a monopoly, to circumvent a statute, or to protect crime or justify a wrong.

17. In addition to its own acts for which it is liable, Schering/Schering-Plough Corporation as the parent, owner and primary, if not exclusive, shareholder of Warrick

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registered with the Secretary of State for the State of Missouri.

Pharmaceuticals Corporation, is liable for the conduct of any and all agents of Warrick Pharmaceuticals Inc. Schering/Schering-Plough is liable for Warrick's wrongful activities under the equitable doctrines of joint business enterprise, single business enterprise, and alter ego. Each of these theories is advanced in the alternative.

18. The following allegations support piercing the corporate veil for the Schering entities under any or all of these theories. Warrick could not exist without Schering/Schering-Plough. Warrick has only a handful of employees, yet Warrick has generated annual sales of over $150M. Warrick depends upon Schering/Schering-Plough manufacturing, distribution, accounting and administrative departments for all of these internal functions. Warrick apparently does not even employ persons with those traditional business responsibilities. The only personnel Warrick allegedly employs are those who market and sell Schering/Schering-Plough generic products. Warrick business offices are within the offices of Schering/Schering-Plough. Warrick does not conduct its corporate business in Reno, Nevada as its letterhead represents. Instead, Schering/Schering-Plough and Warrick operate from the same office space in New Jersey, use the same computer systems, telephone systems, employees, and centralized departments, and apparently use each other's letterhead interchangeably.

19. The companies are so closely aligned that in a deposition taken in a separate litigation, even the founder of Warrick did not know whether his Warrick consulting contract is with Warrick or Schering/Schering-Plough. These companies are not operated as separate entities, but rather integrate their resources to achieve a common business purpose to sell Schering/Schering-Plough generic products. Whether express or implied, Warrick and Schering/Schering-Plough agreed that Warrick would act as the Schering/Schering-Plough marketing unit for generic products, with the common purpose of selling more of

Schering/Schering-Plough and Warrick products and with Schering/Schering-Plough having at least an equal right to direct and control the operation of the enterprise.

20. Also, Schering/Schering-Plough brand version of Albuterol Sulfate, named "Proventil", was sold in conjunction with Warrick generic Albuterol Sulfate. When Warrick customers purchased enough Warrick generic Albuterol Sulfate, Warrick would then give that customer a credit to obtain Proventil. These companies acted as one rather than as two independent drug manufacturers.

21. Furthermore, Schering/Schering-Plough may have purposefully under capitalized Warrick in light of the nature and risk of its business in order to avoid financial responsibility and allow Schering/Schering-Plough to break the law without suffering the consequences. Allowing the corporate structure to protect Schering/Schering-Plough from these wrongful acts would lead to injustice. In light of the above allegations, Warrick and Schering/Schering-Plough should be treated as one entity for liability purposes in order to insure Plaintiffs can fully and completely recover any judgment rendered in its favor in this matter. Also, Schering/Schering-Plough sells Warrick products to large market segments with full knowledge of the false price representations, as set forth herein, and, therefore, benefits from such sales.

22. The Defendants specified herein are sometimes referred to collectively as the "Defendants" or "Defendant Drug Companies." Any and all acts alleged herein to have been committed by any or all of the Defendant Drug Companies were committed by each Defendant's officers, directors, employees, representatives or agents who at all times acted on behalf of their respective Defendant(s).

23. The Defendants referred to in paragraphs 16 through 22 are all related entities sharing common elements of management, finances, control, supervision, reporting and thus are

mutually, jointly and severally liable under legal theories of Respondent Superior and the past, present and continuing relations and dealings by and between these related entities are so inextricably intertwined that for purposes of this suit, some or all of them can and should be considered as a single entity at law and equity, at least to the point of requiring the entity(s) with the ultimate financial responsibility for the actions of Warrick, over the years since 1994, to be properly before the Court and subject to its jurisdiction. Schering/Schering-Plough concealed its approval, use and recording of the false prices in its records management system.

THE COURT SHOULD DISREGARD THE CORPORATE FICTION FOR DEY, INC.; DEY, L.P.; EMD PHARMACEUTICALS, INC. AND MERCK KGaA

24. The corporate fiction may be disregarded when the corporate form has been used as part of a basically unfair device to achieve an inequitable result, specifically when the corporate fiction is used to perpetrate a fraud, as a mere tool or business conduit of another corporation, as a means of evading existing legal obligations, to achieve or perpetrate a monopoly, to circumvent a statute, or to protect crime or justify a wrong.

25. The following allegations support piercing the corporate veil for the Merck entities. Dey, Inc. is the general partner and owner of a 1% interest of Dey, L.P. Dey, Inc. also owns 100% of the shares of Dey Limited Partners, Inc. Dey Limited Partners, Inc. is the limited partner and owner of a 99% interest in Dey, L.P. EMD owns 100% of the shares of Dey, Inc. Merck, S.A. owns 100% of the shares of EMD. KGaA owns approximately 99.55% of the shares of Merck, S.A. In addition, EMD is the sole shareholder of Dey, Lipha is the sole shareholder of EMD, Merck-Lipha is the sole shareholder of Lipha, and likewise Merck is the sole shareholder of Merck-Lipha. In addition to its own acts, as the exclusive owner of Dey, EMD is liable for the wrongful activities of Dey under the equitable doctrines of joint business

enterprise, single business enterprise, and alter ego. Lipha, in addition to its own acts, as the exclusive owner of EMD, is liable for EMD's acts and omissions under the same theories of joint business enterprise, single business enterprise, and alter ego. Merck-Lipha, in addition to its own acts, as the exclusive owner of Lipha, is liable for Lipha's acts and omissions under the same theories of joint business enterprise, single business enterprise, and alter ego. Similarly, in addition to its own acts, as the exclusive owner of Merck-Lipha, Merck is liable for Merck-Lipha, Lipha , EMD and Dey's acts and omissions under the same theories of joint business enterprise, single business enterprise, and alter ego. Each of these theories is advanced in the alternative.

26. Merck, Merck-Lipha, Lipha, and EMD at all times material were aware that Dey reported inflated price and cost representations to First Data Bank in order to increase reimbursement profit for Dey's provider customers. Merck, EMD, Lipha, and Merck-Lipha required Dey's senior management to keep them informed of sales arising in part from inflated price reports and to keep them informed of Dey's actions to create and exploit reimbursement spreads. Merck, EMD, Lipha, and Merck-Lipha utilized Dey to perpetrate the fraud on the MMP as alleged herein. Merck, EMD, Lipha, and Merck-Lipha exercised direct managerial control and direction over Dey, including the actions of Dey herein.

27. The Defendants specified herein are sometimes referred to collectively as the "Defendants" or "Defendant Drug Companies." Any and all acts alleged herein to have been committed by any or all of the Defendant Drug Companies were committed by each Defendant's officers, directors, employees, representatives or agents who at all times acted on behalf of their respective Defendant(s).

28. The Defendants referred to in paragraphs 24 through 27 are all related entities

sharing common elements of management, finances, control, supervision, reporting and thus are mutually, jointly and severally liable under legal theories of Respondent Superior and the past, present and continuing relations and dealings by and between these related entities are so inextricably intertwined that for purposes of this suit, some or all of them can and should be considered as a single entity at law and equity, at least to the point of requiring the entity(s) with the ultimate financial responsibility for the actions of Dey, over the years since 1994, to be properly before the Court and subject to its jurisdiction.

III. JURISDICTION AND VENUE

29. This Court has jurisdiction over the subject matter of this action pursuant to Chapter 27, Chapter 191 and Chapter 407 of the Revised Statutes of the State of Missouri and pursuant to Article V of the Missouri Constitution. This Court also has subject matter jurisdiction "over Plaintiff's claims for injunctive relief based on alleged violations of state consumer protection law with respect to fraud...".[4]

30. This Court has personal jurisdiction over each Defendant because each has registered to do business in the State of Missouri or is doing business in the State of Missouri.

31. Jurisdiction over the subject matter is based upon the MHCPFAA and MMPA, both of which prohibit the conduct of the Defendants and provide exclusive remedies to redress such conduct.

32. Venue lies in the Circuit Court of the City of St. Louis, Missouri, pursuant to Section 508.010 in that many of the unlawful acts committed by the Defendants were

[4]See State ex rel. Jeremiah W. (Jay) Nixon v. Nextel West Corp., et al., 248 F. Supp.2d 885,893 (E.D.Mo.2003)(Plaintiff's motion to remand granted, with finding of improper removal and award of attorney fees).

committed in St. Louis City, Missouri, including the making of false statements and misrepresentations of material fact to the State of Missouri, its departments, agencies, instrumentalities, contractors and to the MMP.

FACTUAL BACKGROUND

MISSOURI MEDICAID PROGRAM

33. Pursuant to the provisions of the Social Security Act (42 U.S.C. § 301 *et seq.*), Chapter 208, RSMo, and regulations promulgated thereto, the State of Missouri, through its Department of Social Services (DSS), Division of Medical Services (DMS), administers the Missouri Medicaid Program (MPP), a "Medical assistance program" as defined by Section 191.900(8), providing for medical, dental, and prenatal care for indigent and low income persons in the State of Missouri.

34. Defendants are "Health care providers", as defined by Section 191.900(7) RSMo; deliver "Health care", as defined by Section 191.900(4) RSMo; and receive "Health care payments", as defined by Section 191.900(6) RSMo; from a "Medical assistance program," as defined by Section 191.900(8) RSMo.

35. Funding for the Medicaid program is provided by both federal grant funding and the general revenue of the State of Missouri.

36. In accordance with 13 CSR 70-3.020, *et seq.*, the MMP reimburses enrolled providers for a multitude of health care products, including prescription drugs provided to Medicaid recipients. Defendants manufacture and sell prescription drugs to providers who then dispense those drugs to Medicaid recipients.

37. To be reimbursed for a provided product, enrolled providers are required to submit a medical claim. In the case of pharmacies, such claims may be submitted either via

form MO-8803, (Revision 09/99) or POS, on-line claim format – NCPDP current version. By either claim method, the provider is required, *inter alia*, to specifically identify the Medicaid beneficiary receiving the drug, the medication dispensed by the National Drug Code (NDC), the quantity dispensed, the date of service, and the total charge for all services claimed.

38. The amount MMP reimburses providers for the drugs dispensed is governed by various Missouri laws and regulations that include Average Wholesale Price ("AWP") and Wholesaler Acquisition Cost ("WAC"). AWPs and WACs are published for each drug identified by a National Drug Code (NDC).

39. The Missouri Code of State Regulations, 13 CSR 70-20.070, defines drug reimbursement methodology:

"(3) Reimbursement for covered drugs will be made at the lower of the

(A) Usual and customary charge as billed by the provider; or

(B) Price(s) on the Drug Pricing File, which is derived from one (1) or more of the following:

1. The AWP as furnished by the state's contracted agent, less ten and forty-three hundredths percent (10.43%);
2. The MMAC (Missouri Maximum Allowable Cost) as determined by the state agency for selected multiple source drugs; and
3. Applicable federal upper limits as found at **www.dss.state.mo.us/dms**; or
4. The WAC as furnished by the state's contracted agent, plus ten percent (10%)."

40. NDCs are the universal product identifiers for drugs for human use; the Food and Drug Administration assigns the first part of the NDC, which identifies the firm that manufactures, repackages, or distributes a drug. Each NDC is specific to a chemical entity,

dosage form, manufacturer, strength, and package size. For example, a drug made by one manufacturer in one form and strength, but in three package sizes, would have three NDCs. Likewise, a drug manufactured in the same form and strength, but by a different manufacturer, would have a different NDC.

41. GTE Data Services Incorporated (GTE), a private company, served, pursuant to contract, as a fiscal agent for DSS, DMS. On August 1, 2000, the name of the fiscal agent changed, due to corporate mergers, from GTE to Verizon Data Services, Inc. (hereinafter, Verizon). On October 1, 2004, the name of the fiscal agent changed to Infocrossing Healthcare Services, Inc. (hereinafter, Infocrossing). MMP providers experienced no other changes. As fiscal agent, Infocrossing/Verizon/GTE, receives and processes Medicaid claims submitted by healthcare providers.

42. For drug pricing information, MMP contracted with First Data Bank, which compiles the National Drug Data File, to provide a weekly computer-generated tape which provides the information needed to price all fee-for-service Medicaid drug claims. The tape contains the National Drug Code (NDC), drug name, drug strength, dosage form, package size, AWP, prices set by direct-selling manufacturers (direct prices), WAC, and federal Health and Human Services upper limits for specified multiple source drugs. MMP adjusts the price it pays for drugs based on the information provided by First Data Bank.

43. When a drug claim is received from a provider it is processed through a computer algorithm, which determines the appropriate per unit reimbursement, applies the appropriate pharmacy dispensing fees, and authorizes payment to the pharmacy.

44. When a Medicaid recipient presents a valid prescription to a provider for a certain type of medication, the provider must select the generic drug of the same active chemical

ingredients of the same strength, quantity, and dosage form unless specifically authorized to provide the brand name medication.

45. In many instances, the provider has the choice of dispensing one of several pharmaceutically equivalent drugs to the recipient.

DEFENDANTS' "MARKETING THE SPREAD" SCHEME

46. Defendants sold prescription drugs to providers and wholesalers at prices that were generally and currently available in the marketplace and carefully set and maintained business records of such prices. However, the Defendants reported, or caused the reporting of prices to MMP through First Data Bank, in the form of average whole prices (AWP) and wholesaler acquisition costs (WAC), that the Defendants knew were substantially greater than the prices generally and currently available in the marketplace to prudent purchasers. The Defendants thus arranged financial incentives for purchasers of their drugs in the form of the enhanced spread between the reimbursement amount resulting from their false and misleading price representations and the actual price of the drugs. This practice of creating and exploiting the enhanced spread between the providers' cost and the reimbursement amount is sometimes referred to as "marketing the spread" (hereinafter sometimes referred to as the "scheme").

47. Three drugs that the Defendants marketed in Missouri and on which they artificially increased the spread are Albuterol, Albuterol Sulfate and Ipratropium Bromide, which are prescribed for respiratory conditions.[5]

48. Each of the Defendants also offered other remuneration and financial incentives to providers to stimulate sales of their drugs. These incentives, included free samples of their

[5]A list of the drugs sold in Missouri is attached as Exhibit A.

drugs, volume discounts, rebates, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness and grants. All of these incentives were designed to lower the providers' net cost of purchasing the Defendants' drugs while concealing the actual cost price beneath a high invoice price, thereby increasing their "spread".

49. In accordance with 13 CSR 70-3.020, *et seq.*, the MMP must "obtain, by contract with a reputable medical publishing company a weekly computer-generated tape which will provide the information needed to price all fee-for-service Medicaid drug claims." MMP contracted with First Data Bank for the weekly tape. The Defendants reported to First Data Bank drug prices – AWP and WAC – that are deliberately false and fictitious to cause Plaintiffs to overpay for drugs.

50. First Data Bank reports prices each week based on information reported, or caused to be reported, to it by the various drug companies for their respective drugs. First Data Bank reports all pricing information as reported, or caused to be reported, by the drug companies, without independent review of those prices for accuracy. Instead, First Data Bank relies on the drug companies to update their reported prices. By this simple process, the Defendants control the prices reported to MMP as the AWPs and WACs for each drug.

51. The providers financially benefitted by the enhanced "spread" between the AWP and/or the WAC and the actual cost paid for the drug, while the Defendants intended to benefit by maintaining and increasing their market share and sales volume for the drugs benefitted by increasing their market share, sales volume and profits for their drugs.

52. Defendants actively concealed and failed to disclose the facts alleged herein. Plaintiffs have been kept in ignorance of vital information essential to knowledge of and pursuit of these claims, without any fault or lack of diligence on their part. The Plaintiffs did not

become aware of the Defendants' fraud scheme until it was disclosed by an industry insider that has assisted the federal and state governments in conducting ongoing investigations and pursuing actions against the Defendants. Plaintiffs were diligent in pursuing an investigation of the claims asserted in this Petition and could not reasonably have discovered the fraudulent nature of the published AWPs and WACs. Defendants knew the Plaintiffs were bound by statute and regulation to accept the prices reported by First Data Bank, a reputable medical publishing company.

53. Defendants concealed that:

A. their AWPs and WACs were highly-inflated and were inflated to cause MMP to overpay for the subject drug;

B. they were manipulating the AWPs and WACs of the subject drugs; and

C. the AWPs and WACs bore no relationship to the prices paid for, or the pricing structure of, the subject drugs as they were sold to providers.

54. The Defendants knew that reporting false drug prices and costs would cause the MMP to pay excessive reimbursement to Medicaid providers. Internal documents demonstrate Defendants' knowledge of the impact of their actions on drug pricing.

55. The Defendants were each fully capable of making truthful representations about prices and costs of the specified drugs and did so when it was economically beneficial to them. Notwithstanding the Defendants' knowledge that they were required to provide truthful price information vital to MMP's ability to determine the acquisition costs, the Defendants each knowingly or intentionally reported or caused the reporting of false price information about the specified drugs.

56. Defendants failed to disclose certain information "with the intent to obtain a health care payment to which the health care provider or any other health care provider is not

entitled or to obtain an amount greater than that which the health care provider is entitled".

57. Defendants knowingly solicited and received remuneration, directly and indirectly, overtly and covertly, in cash and in kind in return for providing false prices to be used for determining Medicaid drug claim reimbursement in violation of Section 191.905 RSMo. The Defendants further arranged for the purchasers of their drugs to receive remuneration, directly and indirectly, overtly and covertly, in cash and in kind, in exchange for their purchases of drugs for which MMP paid reimbursement in violation of Section 191.905 RSMo.

58. The Defendants' acts and omissions were intended to defraud the MMP and the taxpayers in the State of Missouri who fund the various MMPs.

59. Such activities began before 1994 and continue in some form to the present date.

60. The officers, managers, sales force, and other employees of each Defendant within its ranks entered into an agreement, combination or conspiracy among themselves as follows:

A. By reporting false drug prices;

B. By failing to timely update and report declining drug prices;

C. By reporting false drug prices to recognized industry price reporting services to further their scheme; and

D. By directly and indirectly causing their own sales and marketing force employees to "market the spread" by advertising and urging enrolled MMP providers to purchase and dispense their particular brand of drugs, based upon artificially inflated reimbursement amounts made possible by the combined actions of the Defendants and others in the industry.

COUNT I

False Claims – §191.905(1), RSMo.

61. Plaintiffs reallege and incorporate by this reference as if fully set forth herein the allegations of paragraphs1 through 60 of this Petition.

62. Defendants knowingly made or caused to be made false statements or false representations of material facts in order to receive health care payments from MMP, in violation of Section 191.905.1, RSMo, starting in or about 1994 and continuing to this date as follows:

A. Defendants knowingly provided First Data Bank inflated and fraudulent drug pricing information. Specifically, Defendants provided First Data Bank with, or caused First Data Bank to be provided with, or to calculate AWPs and WACs, which were false and intentionally misleading, knowing that MMP relies upon the drug pricing information Defendants report to set the reimbursement rate for Medicaid providers; and

B. Defendants knowingly market Albuterol, Albuterol Sulfate and Ipratropium Bromide to providers based on the "spread," thereby resulting in payment of a greater sum than earned.

63. Plaintiffs were unaware of the foregoing false representations, circumstances and conduct of Defendants and in reliance on said false and fraudulent information, authorized payments for Defendants' medications, and as a result have been damaged.

64. Pursuant to Section 191.905.8, RSMo, each separate false statement or false representation of a material fact constitutes a separate violation of the Health Care Payment Fraud and Abuse Act and is actionable. Each time an enrolled Medicaid provider submits a claim for Defendants' Albuterol, Albuterol Sulfate and/or Ipratropium bromide, Defendants have made or caused to be made a false statement or false representation of a material fact.

65. Pursuant to Section 191.905.11, RSMo, Defendants are liable for civil money penalties of not less than $5,000.00 and not more than $10,000.00 for each separate false claim plus three (3) times the amount of damages which the MMP program sustained, because of the Defendants' acts. Defendants are also required to reimburse the Plaintiffs for reasonable costs attributable to this litigation.

WHEREFORE, Plaintiffs pray that this Court enter judgment against Defendants Dey, Inc.; Dey, L.P.; EMD Pharmaceuticals, Inc.; and Merck KGaA and against Defendants Warrick Pharmaceuticals Corporation, Schering-Plough Corporation and Schering Corporation as follows:

A. Enter judgment in favor of Plaintiffs and against Defendants for three (3) times the amount of damages the Plaintiffs sustained as a result of the Defendants' acts as provided by Section 191.905.11, RSMo;

B. Assess against Defendants a civil penalty of not less than $5000.00 nor more than $10,000.00 for each of the separate claims Defendants caused to be submitted, which violated the Health Care Payment Fraud and Abuse Act as provided by Section 191.905.8, RSMo;

C. Assess against Defendants the investigative costs, costs of suit, and attorneys' fees incurred by Plaintiffs; and

D. Issue any and all other relief which the Court deems just and proper to the investigation and prosecution of this action.

COUNT II

Fraudulent Misrepresentation

66. Plaintiffs reallege and incorporate by this reference as if fully set forth herein the allegations of paragraphs 1 through 65 of this Petition.

67. Defendants represented to First Data Bank and, subsequently to MMP, the AWPs and WACs for Albuterol, Albuterol Sulfate and Ipratropium Bromide.

68. Defendants made false representations of the AWPs and WACs for Albuterol, Albuterol Sulfate and Ipratropium Bromide multiple times between 1994 to present.

69. Defendants knew the AWPs and WACs reported to First Data Bank and, subsequently MMP, were false and misleading when made.

70. The false representations were material to Plaintiffs' decisions concerning payment of Medicaid claims.

71. Defendants knew or should have known that MMP must, pursuant to the CSR, rely on the AWPs and WACs Defendants provided and pay excessive drug reimbursements.

72. MMP was unaware that Defendants provided false and misleading AWPs and WACs.

73. MMP reasonably relied on the truth, veracity and accuracy of the drug pricing information provided by Defendants.

74. As a result of Defendants' false representations, MMP paid excessive drug claim reimbursements for Defendants' Albuterol, Albuterol Sulfate and Ipratropium Bromide between 1994 to present.

75. The conduct of Defendants was outrageous because of Defendants' evil motives or reckless indifference to the rights of Plaintiffs.

WHEREFORE, Plaintiffs pray that this Court enter judgment against Defendants Dey, Inc.; Dey, L.P.; EMD Pharmaceuticals, Inc.; and Merck KGaA and against Defendants Warrick Pharmaceuticals Corporation, Schering-Plough Corporation and Schering Corporation as follows:

A. Enter judgment in favor of Plaintiffs and against Defendants for a fair and reasonable amount as restitution for the benefits fraudulently received, plus interest;

B. Enter judgment in favor of Plaintiffs and against Defendants for a fair and reasonable amount as disgorgement of unjust enrichment;

C. Enter judgment in favor of Plaintiffs and against Defendants for punitive damages in an amount that will deter similar outrageous conduct;

D. Enter judgment in favor of Plaintiffs and against Defendants for the investigative costs, costs of suit and attorneys' fees incurred by Plaintiffs; and

E. For such other relief as this Court deems just and proper.

COUNT III

UNLAWFUL TRADE PRACTICES PROHIBITED BY SECTION 407.020 ET SEQ.

76. Plaintiffs adopt and reallege paragraphs 1 through 75 of this Petition, as if fully set forth herein.

77. Defendants knew that reporting false drug prices, costs or sales information would cause the MMP to be unable to reasonably estimate acquisition costs and would thus pay excessive reimbursement to the Defendants' provider customers.

78. Notwithstanding this knowledge, the Defendants reported false or misleading price, cost, or sales information to First Data Bank, directly causing the MMP program to pay claims for their specified drugs in amounts that exceeded both the prices at which the Defendants actually sold their products and the reasonable estimation of acquisition cost paid by providers.

79. This reporting of false information created a "spread" between the amount reimbursed by the Plaintiffs and the much lower actual acquisition cost paid by the provider to purchase the drugs.

80. The "spread" financially benefitted Defendants. By giving their providers the incentive to dispense the Defendants' specified drugs, rather than a competitor's drug, Defendants increased their respective market share.

81. The Defendants were each fully capable of making truthful representations about prices, costs and sales of the specified drugs and did so when it was economically beneficial to them.

82. Notwithstanding the Defendants' knowledge that they were required to provide truthful price information to First Data Bank, knowing such truthful reporting was vital to MMP's ability to estimate the acquisition cost, the Defendants each knowingly or intentionally reported false price information about the specified drugs.

83. The officers, managers, sales force and other employees of the named Defendants herein acted, used or employed, deception, fraud, misrepresentation, unfair practice or the concealment, suppression, or omission of material fact, in the sale or advertisement of drugs, by:

A. Reporting false drug prices, for specified drugs to be covered by MMP;

B. Omitting or refusing to timely update and report decreases in the prices or costs of specified drugs;

C. Concealing or otherwise failing to disclose transactions that decrease the cost, and thereby the price, of the specified drugs such as discounts, rebates, off-invoice pricing, free goods, cash payments, charge backs, or other financial incentives;

D. Falsely reporting that the price or cost of a specified drug was increasing when it in fact was increasing in a lesser proportion, or remained the same, or was decreasing;

E. Falsely reporting that the price or cost of a specified drug was the same when in fact it was falling;

F. Concealing the material fact that they have not disclosed that the reported AWP and WAC do not reflect the true average wholesale price or wholesaler acquisition cost of the drug products they sell, while concealing the fact that the reported AWP and WAC are inflated, causing increased prices to be paid by others, including the State of Missouri;

G. Concealing, suppressing or omitting to disclose the material fact that they had misrepresented the true AWP and WAC paid for their drugs causing increased prices to be paid by others, including the State of Missouri;

H. Making false representations that the reported AWP and WAC are accurate;

I. Reporting false drug prices to recognized industry price reporting services so as to create a wrongful "spread" which induced the payment of inflated and excessive reimbursement amounts for Defendants' drugs; and

J. Committing an unfair trade practice by causing their own sales and marketing force employees, as well as independent contractor telemarketers, to "market the spread" by advertising and urging providers to purchase and dispense their particular brand of drugs based upon the wrongfully inflated reported AWP and WAC, causing excessive reimbursement amounts to be paid by others, including the State of Missouri.

84. The Defendants acted knowingly or intentionally in making false statements and misrepresentations of material fact when reporting false prices or costs to the MMP.

85. These acts and omissions were committed by the named Defendants, knowing that the State of Missouri officials would rely upon such false information and that such acts and omissions would present a risk of, or cause, substantial injury to consumers.

86. The acts and omissions of Defendants, as aforesaid, offend the public policy, as set forth in Section 191.900 and violate Section 407.010 through 407.130 and 15 C.S.R. 60-

8.020.

87. Section 407.020 provides, in part:

> The act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce or the solicitation of any funds for any charitable purpose, as defined in section 407.453, in or from the State of Missouri, is declared to be an unlawful practice.
>
> * * *
>
> Any act, use or employment declared unlawful by this subsection violates this subsection whether committed before, during or after the sale, advertisement or solicitation.

88. To administer and enforce the provisions of the MMPA, a State regulation promulgated as 15 C.S.R. 60-8.020, specifies the settled meaning of "unfair practice in general" to be:

> 1. An unfair practice is any practice which —
> 1. Either
> 1. Offends any **public policy** as it has been established by the Constitution, **statutes or common law of this state**, or by the Federal Trade Commission, or its interpretive decisions; or
> 2. Is unethical, oppressive or unscrupulous; and
>
> B.) Presents a risk of, or causes, substantial injury to consumers.
>
> 2. Proof of deception, fraud, or misrepresentation is not required to prove unfair practices as used in Section 407.020.1., R.S.Mo. (See *Federal Trade Commission v. Sperry and Hutchinson Co.,* 405 U.S. 233, 92 S.Ct.898, 31 L.Ed.2d 170 (1972); *Marshall v. Miller,* 302 N.C. 539, 276 S.E.2d 397 (N.C. 1981); see also, Restatement, Second, Contracts, Sections 364 and 365). (Emphasis added.)

89. Further, Section 407.100.1-3 provides:

> 1. Whenever it appears to the attorney general that a person has engaged in, is engaging in, or is about to engage in any method, act, use, practice or solicitation or any combination thereof, declared to be unlawful by this

chapter, he may seek and obtain, in an action in a circuit court, an injunction prohibiting such person from continuing such methods, acts uses, practices or solicitations or any combination thereof, or engaging therein, or doing anything in furtherance thereof.

2. In any action under subsection 1 of this section, and pursuant to the provisions of the Missouri Rules of Civil Procedure, the attorney general may seek and obtain temporary restraining orders, preliminary injunctions, temporary receivers and the sequestering of any funds or accounts if the court finds that funds or property may be hidden or removed from this state or that such orders or injunctions are otherwise necessary.

3. If the court finds that the person has engaged in, is engaging in, or is about to engage in any method, act, use, practice or solicitation, or any combination thereof, declared to be unlawful by this chapter, it may make such orders or judgments as may be necessary to prevent such person form employing or continuing to employ or to prevent the recurrence of, any prohibited methods, acts, uses, practices or solicitations, or any combination thereof, declared to be unlawful by this chapter.

90. Section 407.010(6) defines "sale" as "any sale, lease, offer for sale or lease, or attempt to sell or lease merchandise for cash or on credit."

91. Section 407.010(1) defines "advertisement" as " the attempt by publication, dissemination, solicitation, or circulation, or any other means to induce, directly or indirectly, any person to enter into any obligation or acquire any title or interest in any merchandise."

92. Section 407.010(4) defines "merchandise" as any "objects, wares, goods, commodities, intangibles, real estate or services."

93. Section 407.010(7) defines "trade" or "commerce" as "the advertising, offering for sale, sale, or distribution, or any combination thereof, of any services and any property, tangible or intangible, real, personal, or mixed, and any other article, commodity, or thing of value wherever situated. The terms 'trade' and 'commerce' include any trade or commerce directly or indirectly affecting the people of this state."

94. The wrongful conduct alleged in this Complaint occurred and continues to occur in the ordinary course of Defendants' business or occupation and has caused great harm to the State of Missouri and its residents, who were foreseeable and direct victims of Defendants' wrongful conduct.

WHEREFORE, the Plaintiffs pray for relief as follows:

A. That the Court adjudge and decree that Defendants have engaged in the conduct alleged herein;

B. That the Court adjudge and decree that Defendants' conduct is unlawful;

C. That the Court enjoin and restrain Defendants and their officers, agents, servants, and employees, and those in active concert or participation with them, from continuing to engage in such conduct or other conduct having similar purpose or effect;

D. That the Court enjoin and restrain Defendants and Order that any and all future disseminations of AWP and WAC accurately reflect the average wholesale prices and wholesaler acquisition costs paid by providers;

E. That the Court, pursuant to Section 407.100, enter an Order of restitution to the State of Missouri for all monies paid as a result of Defendants' unlawful practices;

F. That the Court, pursuant to Section 407.130, enter an Order in favor of the State of Missouri to recover from Defendants the costs of this action, including expert fees and reasonable attorneys' fees;

G. That the Court, pursuant to Mo. Rev. Stat. Section 407.100.6, enter an order in favor of the State of Missouri for civil penalty of one thousand dollars ($1,000.00) per violation of law; and

H. That the Court Order such other and further relief as it may deem just, necessary and appropriate.

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Index of Acronyms

AWP - Average Wholesale Price

DMS - Division of Medical Services

DSS - Department of Social Services

GTE - GTE Data Services Incorporated

MHCPFAA - Missouri Health Care Payment Fraud and Abuse Act

MMPA - Missouri Merchandising Practices Act

MMP - Missouri Medicaid Program

MMAC - Missouri Maximum Allowable Cost

NDC - National Drug Code

WAC - Wholesaler Acquisition Cost

EXHIBIT B